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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,016	12/12/2005	Hajimu Kurumatani	TAN-05-1715	4525

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,016	KURUMATANI ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21* is/are pending in the application.

4a) Of the above claim(s) *17,18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-16) and beraprost sodium as the species of formula I, in the reply filed on July 22, 2008 is acknowledged.

Applicant submitted an information disclosure statement (IDS) on January 23, 2006. Reference AM (JP 11 189536A) was not in English, and there was no summary or translation provided so it was not considered. Reference AN (WO 00/67748 A1) had only an abstract present in English, and as such only the abstract was considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 15-16 applicant has claimed a prophylactic agent for renal disease however applicant has not disclosed their invention such that one of skill in the art at the time of the invention could use their invention as claimed to prevent renal disease.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation necessary would be large (1) due to the complete lack of direction or examples directed towards prevention of renal disease (2,3). The nature of the invention is a compound to prevent a variety of diseases (4) and the breadth of the claims is quite large because renal diseases encompasses quite a large number of complicated and diverse diseases such as diabetic nephropathy, interstitial nephritis, and renal failure (8). The state of the prior art is such that prevention of renal disease is not known (5) and while the skill of those in the art is very high (6) the unpredictability of prophylactic treatments is also very high (7).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5-11, applicant claims the enhancing agent of claim 1, wherein the renin-angiotensin system inhibitor (claims 5-9) or the renal disease (claim 11) is a specific compound however claim 1 never actually comprises a renin-angiotensin system inhibitor or a patient with renal disease. In fact claim 1 is a composition (and applicant has elected the composition over the method of treating claims), and therefore the intended use (to enhance the effect of renin-angiotensin system inhibitors in patients with renal disease) does not hold patentable weight. Furthermore, the compounds and diseases being claimed in claims 5-11 are not even claimed in claim 1. Therefore it is unclear what applicant is claiming in claims 5-11, as the elements being claimed are not required or contained in the composition of claim 1.

In claims 12-14, applicant claims the agent of claim 1, wherein the effect results in various outcomes. However as discussed above, claim 1 is drawn to a composition and not a method, and therefore there is not effect of claim 1 and it is unclear what applicant is attempting to claim in claims 12-14.

Since applicant has failed to point out and distinctly claim the subject matter which applicant regards as the invention, claims 5-14 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Uekama et al. (US 5,854,281).

In claim 1 applicant claims an enhancing agent comprising as an effective ingredient a prostaglandin I derivative of formula I, and applicant has elected beraprost sodium as the elected species of formula I. Since claim 1 is a composition and only comprises beraprost sodium, claims 1-14 are directed to an agent comprising beraprost sodium. Uekama et al. teaches beraprost sodium as part of their composition (columns 3-4) and Uekama et al. anticipates claims 1-14.

It is noted that claims 5-14, while they claim various angiotensin inhibitors or specific renal diseases lack antecedent basis for those additional compounds as discussed above, and since there is no "further comprising" language, claim 1 does not require those components, and the claims are directed towards compositions and thus intended use is not patentable the additional limitations of claims 5-14 carry no patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosoglou et al. (US 2003/0069221 A1).

As discussed above, in claims 1-14, applicant claims a composition comprising beraprost sodium, and in claims 15-16 applicant claims a composition/kit that comprises beraprost sodium and a renin-angiotensin system inhibitor. Kosoglou et al. teaches ACE inhibitors as angiotensin system inhibitors (page 4, [0026-0028]) as well as

beraprost sodium (page 29, [0435]) as parts of their composition for treatment of various disorders such as diabetes (abstract). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that the method of Kosoglou et al. contains both an angiotensin system inhibitor and beraprost sodium and thus claims 1-16 are unpatentable over Kosoglou et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-

3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614